4-26-95

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the application of	)	Examiner M. Thaler
PAUL G. YOCK	)	Group 336 #15
For ANGIOPLASTY APPARATUS FACILITATING RAPID EXCHANGES AND METHOD	)	
Serial No. 07/528,729	)	
Filed May 24, 1990	)	
Atty. Docket D-0024/31609	)	

July 15, 1991

CROSBY, HEAFEY, ROACH & MAY
Los Angeles, California

CERTIFICATE OF MAILING UNDER 37 CFR §1.10
I hereby certify that this correspondence is being deposited with the United States Postal Service in an envelope as "Express Mail Post Office to Addressee" mailing Label No. B 055957 55 addressed to the: Commissioner of Patents and Trademarks Washington, DC 20231 on July 15 1991

July 15 1991
CECILY ANNE SNYDER

POWER OF ATTORNEY BY INVENTORS
REVOCATION OF PRIOR POWERS

The Commissioner
United States Patent
and Trademark Office
Washington, DC 20231

Dear Sir:

As the above named inventor for the above-referenced application, I hereby revoke all powers of attorney previously given and hereby appoint the following attorneys to

prosecute and transact all business in the Patent and Trademark Office connected therewith:

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Respectfully submitted,

Dated: 7/16/91

Paul G. Yock

an inner lumen which extends between the distal guidewire opening and the proximal guidewire opening and which is configured to slidably receive a guidewire therein, and

a proximal shaft section much longer than the distal shaft section;

b) means on the distal shaft section to perform an intravascular procedure which is spaced closer to the distal guidewire opening than the proximal guidewire opening; and

c) a guidewire which is longer than the catheter to extend out of the distal end of the catheter into the patient's coronary artery beyond the location therein where the procedure is to be performed and which is slidably disposed within the inner lumen extending between the distal guidewire opening and the proximal guidewire opening.

23. (Twice Amended) An elongated balloon dilatation catheter assembly for performing an angioplasty procedure at a location within a patient's coronary artery which has means for the rapid exchange of a balloon dilatation catheter over a guidewire without the utilization of an exchange wire or an extension wire, comprising:

a) [an] the elongated balloon dilatation catheter [which is] being configured for percutaneous introduction into a patient's femoral artery and advancement into the patient's coronary artery and [which has] having

[a] an elongated catheter shaft with proximal and distal ends, an inflation lumen and a guidewire receiving lumen extending [therein],

a distal guidewire opening in the distal end of the catheter shaft in fluid communication with the guidewire lumen,

a proximal guidewire opening spaced a short distance proximally from the distal guidewire opening and a substantial distance from the proximal end of the catheter shaft and in fluid communication with the guidewire lumen;

an inflatable dilatation balloon on a distal shaft section having proximal and distal ends, with the distal end of the balloon being spaced closer to the distal guidewire opening than the proximal end of the balloon is spaced from the proximal guidewire opening, and having an interior which is in fluid communication with the inflation lumen; and

b) [a] the guidewire [which is] being sufficiently long to be advanced through the patient's femoral artery and into the patient's

coronary artery beyond the location therein where the angioplasty procedure is to be performed and [which is] being slidably disposed within the guidewire lumen of the balloon dilatation catheter [and which has a portion extending out the distal port and a portion extending out of the proximal port].

24. (Twice Amended) A method for performing an intravascular procedure at a desired location within a patient's artery, comprising:

a) providing an elongated guidewire within the patient's vasculature having an elongated core member with a helical coil on a shapable distal portion thereof, with [a] the distal portion of the guidewire extending within the patient's artery and crossing the desired location therein for performing an intravascular procedure and a proximal portion which extends out of the patient;

b) providing an intravascular catheter comprising:

an elongated catheter shaft having proximal and distal ends and a guidewire receiving inner lumen extending therein to the distal end of the shaft,

a distal guidewire opening in the distal end of the catheter shaft in fluid communication with the guidewire receiving inner lumen,

a proximal guidewire opening spaced a relatively short distance proximally from the distal guidewire opening and a relatively long distance from the proximal end of the catheter shaft in fluid communication with the guidewire receiving inner lumen, and

means to perform an intravascular procedure on a distal portion of the catheter shaft between the proximal and distal guidewire openings which is configured to perform said procedure in a patient's artery and which is spaced closer to the distal guidewire opening than the proximal guidewire opening,

c) mounting the intravascular catheter onto the proximal portion of the guidewire which extends out of the patient with the proximal portion of the guidewire being slidably disposed within the guidewire-receiving lumen of the intravascular catheter and extending out the proximal guidewire opening;

d) introducing the intravascular catheter into the patient's vasculature over the guidewire, while holding a portion of the guidewire which extends out of the proximal guidewire opening in position and advancing the catheter therein until the means to perform an intravascular procedure is positioned within [a] the desired location within the patient's artery, the distal port is within the patient's artery

distal to the desired location and the proximal port is within the patient's artery proximal to the desired location;

e) performing an intravascular procedure at the desired location within the artery by said means; and

f) withdrawing the intravascular catheter from the patient.

25. (Twice Amended) A method for performing a balloon dilatation angioplasty procedure at a desired location within a patient's coronary artery, comprising:

a) providing an elongated guidewire within the patient's vasculature having an elongated core member and a helical coil on a shapable distal portion of the guidewire, with [a] the distal portion of the guidewire extending within the patient's coronary artery and crossing [a] the desired location therein for performing a balloon dilatation angioplasty procedure and with a proximal portion extending out of the patient;

b) providing a balloon dilatation catheter comprising:

an elongated catheter shaft having proximal and distal ends, an inflation lumen and a guidewire receiving lumen and being configured for percutaneous introduction into the patient's arterial system,

a distal guidewire opening in the distal end of the catheter shaft in fluid communication with the guidewire receiving lumen,

a proximal guidewire opening spaced a relatively short distance proximally from the distal guidewire opening and a relatively long distance from the proximal end of the catheter shaft in fluid communication with the guidewire receiving lumen,

a dilatation balloon on a distal portion of the catheter shaft which has an interior in fluid communication with the inflation lumen extending within the shaft and which is spaced closer to the distal guidewire opening than the proximal guidewire opening,

c) mounting the balloon dilatation catheter onto the proximal portion of the guidewire which extends out of the patient with the proximal portion of the guidewire being slidably disposed within the guidewire-receiving lumen of the balloon dilatation catheter and extending out the proximal guidewire opening;

d) percutaneously introducing the balloon dilatation catheter into the patient's arterial system over the guidewire and advancing the balloon dilatation catheter therein, while holding a portion of the

guidewire which extends out of the proximal guidewire opening in position, until the dilatation balloon on the balloon dilatation catheter is positioned within a desired location within the patient's coronary artery;

e) inflating the dilatation balloon at the desired location within the coronary artery to perform the balloon dilatation angioplasty procedure;

f) deflating the dilatation balloon; and

g) withdrawing the balloon dilatation catheter from the patient.

26. (Twice Amended) An elongated balloon dilatation catheter for performing an angioplasty procedure within a patient's coronary artery which has means for the rapid exchange of the catheter over a guidewire without the utilization of an exchange wire or an extension wire, comprising:

a) an elongated catheter shaft having proximal and distal ends and being configured for percutaneous introduction into the patient's femoral artery;

b) a distal guidewire opening in the distal end of the catheter shaft;

c) a proximal guidewire opening in the catheter shaft spaced a short distance proximally from the distal guidewire opening and a substantial distance from the proximal end of the catheter shaft;

d) a flexible distal shaft section configured to be advanceable within the patient's coronary arteries having a guidewire-receiving inner lumen extending proximally from the distal guidewire opening to the proximal guidewire opening and having an inflation lumen coextensive at least in part with the guidewire-receiving inner lumen,

[d]e) an inflatable dilatation balloon on the distal shaft section having proximal and distal ends, [and] having an interior which is in fluid communication with the inflation lumen and being spaced closer to the distal end of the catheter shaft than the proximal guidewire opening; and

[e]f) a proximal shaft section much longer than the distal shaft section which is an elongated tubular member with a single inner lumen extending therein in fluid communication with the inflation lumen in the distal section and which is suitable to advance the distal shaft section within a patient's coronary artery over a guidewire slidably disposed within the guidewire receiving inner lumen.

28. (Twice Amended) An elongated balloon dilatation catheter for performing an angioplasty procedure within a patient's coronary artery which has means for the rapid exchange of the catheter over a guidewire without the utilization of an exchange wire or an extension wire, comprising:

a) an elongated catheter shaft having proximal and distal ends and being configured for percutaneous introduction into the patient's femoral artery;

b) a distal guidewire opening in the distal end of the catheter shaft;

c) a proximal guidewire opening in the catheter shaft spaced a short distance proximally from the distal guidewire opening and a substantial distance from the proximal end of the catheter shaft;

d) a flexible distal shaft section configured to be advanceable within a patient's coronary arteries having

a first inner lumen which extends proximally from the distal guidewire opening to the proximal guidewire opening and which is configured to slidably receive a guidewire therein,

a second inner lumen which is coextensive at least in part with the guidewire-receiving first inner lumen and which is configured to direct inflation fluid therethrough,

a third inner lumen which is coextensive with the first inner lumen and which is configured to be in fluid communication with a second opening in the distal end of the catheter shaft, and

an inflatable dilatation balloon on the distal shaft section having an interior which is in fluid communication with the second inner lumen and being spaced closer to the distal end of the shaft than the proximal guidewire port; and

e) a proximal shaft section much longer than the distal shaft section which is a single elongated tubular member with two inner lumens extending therein, one of the two inner lumens being in fluid communication with the second inner lumen in the distal shaft section and the other inner lumen being in fluid communication with the third inner lumen in the distal shaft section.

30. (Amended) An intravascular assembly which has means for performing a procedure within a region of a patient's body and which is configured for percutaneous introduction into the patient's vasculature, comprising:

a) an intravascular catheter having

an elongated shaft which is [long enough] configured for advancement through the patient's vasculature to the region within the patient's body where the procedure is to be performed and which has proximal and distal ends,

a [relatively short] distal shaft section,

a proximal shaft section much longer than the distal shaft section,

[means on the distal shaft section to perform the procedure,]

a distal guidewire opening in the distal end of the shaft,

a proximal guidewire opening spaced a relatively short distance of at least 10 cm proximally from the [means to perform the procedure] distal end of the shaft and a relatively long distance from the proximal end of the shaft, [and]

means on the distal shaft section to perform the procedure which is configured for percutaneous introduction and advancement into the patient's

vasculature and which is spaced closer to the distal end of the shaft than the proximal guidewire opening,

a guidewire passageway which extends between the distal guidewire [port] opening and the proximal guidewire [port] opening; and

b) a guidewire which has an elongated core member and a helical coil on a distal portion of the core member, which is longer than the catheter and which is slidably disposed within the guidewire passageway to facilitate delivery of the catheter thereover to the region within the patient's body where the procedure is to be performed.

31. (Amended) The intravascular assembly of claim [31] 30 wherein the means to perform the procedure is in communication with an exterior portion of the distal shaft section.

32. (Amended) In an intravascular assembly for performing a procedure within a region of a patient's body which is configured for percutaneous introduction into the patient's vasculature and for intravascular delivery to a region within the patient's body where the procedure is to be performed

a) an elongated catheter which has

an elongated shaft with proximal and distal ends, a [relatively short] distal shaft section and a proximal shaft section much longer than the distal shaft section,

[means to perform the procedure on the distal shaft section,]

a distal guidewire port in the distal end of the shaft,

a proximal guidewire port spaced a relatively short distance proximally from the [means to perform the procedure] <u>distal end of the shaft</u> and a relatively long distance from the proximal end of the shaft, and

<u>means to perform the procedure on the distal shaft section which is configured for percutaneous introduction and advancement within the patient's vasculature and which is spaced closer to the distal end of the shaft than to the proximal guidewire port</u>,

a guidewire passageway which extends between the distal guidewire port and the proximal guidewire port; and

b) an elongated guidewire which is longer than the catheter, which has an elongated core member and a flexible coil on a distal portion of the core member and which is slidably disposed within the guidewire passageway to facilitate advancement of the catheter over the guidewire through the patient's vasculature to said region while maintaining the position of the guidewire within the patient's vasculature.

33. (Amended) In a balloon dilatation catheter assembly for performing an angioplasty procedure within a region of a patient's coronary artery which is configured for percutaneous introduction into the patient's vasculature and for intravascular delivery to [a] the coronary artery where the procedure is to be performed

a) an elongated catheter which has

an elongated shaft with proximal and distal ends, a [relatively short] distal shaft section, a proximal shaft section much longer than the distal shaft section and an inflation lumen extending therein,

[a dilatation balloon on the distal shaft section having an interior in fluid communication with the inflation lumen,]

a distal guidewire port in the distal end of the shaft,

a proximal guidewire port spaced a relatively short distance proximally from the [dilatation balloon] distal end of the shaft and a relatively long distance from the proximal end of the shaft, [and]

a dilatation balloon on the distal shaft section which has an interior in fluid communication with the inflation lumen and which is spaced closer to the distal end of the shaft than to the proximal guidewire port,

a guidewire passageway which extends between the distal guidewire port and the proximal guidewire port; and

b) an elongated guidewire which is at least as long as the catheter, which has an elongated core member and a helical coil on a distal portion of the core member and which is disposed within the guidewire passageway to facilitate advancement of the catheter through the patient's vasculature over the guidewire to the patient's coronary artery while maintaining the position of the guidewire within the patient's vasculature.

34. (Amended) The balloon dilatation catheter assembly of claim 33 wherein the guidewire passageway is at least 10 cm in length.

35. (Amended) An intravascular catheter which has means for performing a procedure within a region of a patient's body and which is configured for percutaneous introduction into the patient's vasculature, comprising:

a) an elongated shaft which is configured for percutaneous introduction into the patient's vasculature, which is long enough for advancement through the patient's vasculature to the region of the patient's body where the procedure is to be performed and which has proximal and distal ends;

b) a [relatively short] distal shaft section;

c) a proximal shaft section much longer than the distal shaft section;

d) [means on the distal shaft section to perform the procedure;

e)] a distal guidewire [port] opening in the distal end of the shaft;

[f]e) a proximal guidewire [port] opening spaced a relatively short distance of at least 10 cm proximally from the [means to

perform the procedure] distal end of the shaft and a relatively long distance from the proximal end of the shaft; [and]

f) means on the distal shaft section to perform the procedure which is configured for percutaneous introduction and advancement within the patient's vasculature and which is spaced closer to the distal end of the shaft than the proximal guidewire opening; and

g) a guidewire passageway [at least 10 cm in length] which extends between the distal guidewire port and the proximal guidewire port and configured to slidably receive a guidewire therein.

36. (Amended) A balloon dilatation catheter for performing an angioplasty procedure within a patient's coronary artery which is configured for percutaneous introduction into the patient's vasculature and for intravascular delivery to the coronary artery where the angioplasty procedure is to be performed, comprising:

a) an elongated shaft with proximal and distal ends, a [relatively short] distal shaft section, a proximal shaft section much longer than the distal shaft section and an inflation lumen extending therein;

b) [a dilatation balloon on the distal shaft section having an interior in fluid communication with the inflation lumen;

c)] a distal guidewire [port] opening in the distal end of the shaft;

[d]c) a proximal guidewire [port] opening spaced a relatively short distance of at least about 10 cm proximally from the [dilatation balloon] distal end of the shaft and a relatively long distance from the proximal end of the shaft; [and]

d) a dilatation balloon on the distal shaft section having an interior in fluid communication with the inflation lumen and being space closer to the distal end of the shaft than the proximal guidewire port;

e) a guidewire passageway [at least 10 cm in length] which extends between the distal guidewire port and the proximal guidewire port and which is configured to slidably receive a guidewire therein.

REMARKS

The applicant wishes to acknowledge with appreciation the Examiner's indication of the allowability of claims 18, 23, 25, 27 and 29. Applicant's amendments to these claims are believed to overcome their rejection under 35 U.S.C. §112 (second paragraph).

In the aforesaid Office Action the Examiner rejected applicant's claim 24 under 35 U.S.C. §103 over Enzmann *et al.*, the Examiner alleging that it would be obvious to hold the portion of the guidewire which extends out of the proximal guidewire port while introducing the catheter in order to stabilize the assembly. The Examiner gives no support to this suggestion either in the cited reference or in other references or is any line of reasoning given for this conclusion. The only discussion in the reference of holding the guidewire in place is when the needle is withdrawn and where pressure is applied to the skin above the vein in which the guidewire is located to hold the guidewire within the vein. However, what the Examiner fails to recognize is that the Enzmann *et al.* catheter is advanced to the desired location by itself after the guidewire is withdrawn, so there is no guidewire to hold in place as suggested by the Examiner. Claim 24 requires the catheter to be advanced over the guidewire to the desired vascular location and this is not suggested by the Enzmann *et al.* reference. Enzmann *et al.* withdraws the guidewire once the catheter is introduced into the patient's vasculature and then the catheter is advanced alone to the desired location. Applicant has also amended claim 24 to require that the proximal port be proximal to the desired location and the distal port be distal to the desired location when the means to perform the procedure is at the desired location.

The applicant believes that claim 24 clearly defines patentable subject matter over the cited reference.

Claims 24, 30-32 and 35 were rejected under 35 U.S.C. §102(b) as anticipated by Uthmann or in the alternative as being unpatentable under 35 U.S.C. §103 as being obvious over Uthmann. However, Uthmann is as deficient as Enzmann *et al.*, as described above, in anticipating or rendering obvious claim 24 and reference is made to the arguments presented above against Enzmann *et al.*. Claims 30-32 require a guidewire with a core member and a coil on a distal portion of the core member. Uthmann describes advancing a catheter over a catheter, not a guidewire and particularly a guidewire having a core member with a coil on its distal extremity. It should be noted that the member 11 of Uthmann is identified as a catheter with the function of returning blood to the same vein from which it was taken. Member 11 is not a guidewire, particularly a guidewire with a core member and a coil on its distal portion. To replace catheter 11 of Uthmann with a guidewire, as seemingly suggested by the Examiner, would preclude return of blood to the same vein and would require a venous puncture for another blood return catheter, which was the very problem Uthmann sought to solve. Thus, Uthmann can neither anticipate nor render obvious claims 30-32. Claim 35 on the other hand requires the proximal guidewire opening to be at least 10 cm from the distal end of the

catheter and a substantial distance from the proximal end of the catheter shaft. There is no teaching in Uthmann in this regard. Note also, as indicated in Fig. 8 of Uthmann, that the proximal port of catheter 12 of the Uthmann device is designed to be located outside of the patient during the procedure, which is contrary to the present invention, where the proximal guidewire port is designed to be within the patient during the procedure.

Claims 26, 28 and 30-36 stand rejected under 35 U.S.C. §103 as being unpatentable over Weikl *et al.*. Applicant has reviewed this reference in detail and believes that it does not suggest the invention claimed in these rejected claims as proposed by the Examiner. All of these claims require the balloon or other means to perform the procedure to be spaced closer to the distal end of the catheter shaft than the proximal guidewire port. Weikl *et al.* on the other hand describes the balloon as being equi-distant from both ports. Additionally, claims 30, 34 and 35 require the proximal port to be at least 10 cm from the distal end of the catheter shaft and there is no suggestion in Weikl *et al.* in this regard. Further, claims 30, 32 and 33 call for a guidewire having a core member and a coil on a distal portion of the guidewire, whereas Weikl *et al.* does not suggest a guidewire, particularly a guidewire with a core and a coil on a distal portion of the guidewire. Member 1 of Weikl *et al.* is identified as a catheter throughout the reference. While it may have a guiding function, it is not a guidewire.

Importantly, member 1 does not have a core member or a coil on a distal portion thereof. As in Uthmann *et al.*, if catheter 1 of Weikl *et al.* is replaced with a conventional guidewire, it would not function as claimed and thus cannot be said to suggest the device as proposed by the Examiner.

The Examiner has also rejected claims 30-32 and 35 under §102(b) as being anticipated by Gants or, in the alternative, as being unpatentable under 35 U.S.C. §103 over Gants. In this rejection, the Examiner has alleged that the Gants catheter is inherently capable of being used in a patient's vasculature or that it is obvious to use the catheter in this manner. The applicant objects to rejection because there has been no reference by the Examiner to anything in this patent which would support the allegation of inherency. The only references regarding the use of the Gants catheter is found in column 2, lines 26-34 and column 3, lines 7-40 of this reference and in both instances it is negative in this regard. As indicated therein, the front surface 34 of balloon 28 is described as being large and flat to prevent entry of the balloon into the patient's urethra. As shown in Fig. 1, the balloon has a flat front surface even in the non-inflated condition. The rejected claims 30-32 and 35 of the present application call for a means to perform the procedure which is configured for percutaneous introduction and advancement within the patient's vasculature. If the catheter of Gants cannot be advanced in the patient's urethra, it surely could

not be percutaneously introduced and advanced within the patient's vasculature. Claims 30 and 35 require the proximal guidewire port to be at least 10 cm from the distal end of the catheter shaft. The catheter of Gants is silent as to the distance of the proximal port from the distal end of the catheter and therefore cannot meet this requirement. Claims 30 and 32 also call for a guidewire with a core member and a coil on a distal portion of the guidewire. The catheter of Gants is just that, a catheter, it is not a guidewire and it does not have a core member and it does not have coil. Thus, the teachings of Gants neither anticipate nor render obvious the presently claimed invention.

Applicant has also filed concurrently herewith a terminal disclaimer as to claims 24 and 25 to avoid the double patenting rejection based upon U.S. Patent No. 5, 040,548.

Applicant submits that the presently pending claims of this application define patentable subject matter and respectfully requests reconsideration and an early allowance of these claims.

Respectfully submitted,

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Attachment: Terminal Disclaimer

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